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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/487,032	06/07/95	SMITH D	GTN-001

HM22/0426

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EXAMINER	
PORTNER, V	
ART UNIT	**PAPER NUMBER**
1641	29

DATE MAILED: 04/26/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/487,032	Smith
Examiner	**Group Art Unit**
Portner	1641

☒ Responsive to communication(s) filed on *Feb 7, 2000* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *113-120, 123-125, 127-135, 149, 150, and 196-213* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *113-120, 123-125, 127-135, 149, 150, and 196-213* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claims 113-120, 123-125,127-135,149-150,196-213 are pending.

Please Note: Rejections and Objections withdrawn will not be addressed at this time. The examiner is reading the word "encodes" to recite open language analogous to the word comprising.

1. In view of the newly published guidelines, the indicated **allowable subject previously indicated is herein withdrawn in view of a new grounds of rejection**. The examiner regrets any inconvenience this may cause Applicant at this time. Please see the Revised Interim Utility Guidelines, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999. In keeping with the revised utility guidelines and corresponding training materials (available on the PTO Website), none of the disclosed uses are specific and substantial.

Rejections Maintained

2. Claims 113-120, 123, 125-141 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record on paper number 26.

3. Claims 120-123,132-135, 149,152, 155 remain rejected under 35 U.S.C. 102(b) as being anticipated by Newman et al (1994)for reasons of record on paper number 26

New Guidelines/New Grounds of Rejection

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 113-120, 123-125,127-135,149-150,196-213 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial, a credible asserted utility or a well established utility.

7. Applicant is directed to the Revised Interim Utility Guidelines, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999. In keeping with the revised utility guidelines and corresponding training materials (available on the PTO Website), none of the disclosed uses is a specific and substantial use.

8. While applicant asserts specific utilities for the claimed invention (use of the polypeptide to treat Helicobacter pylori infection and to stimulate an immune response, these are not considered to be substantial utilities for the following reasons. These utilities are premised on the antigenicity of the polypeptide (SEQ ID NO 764) isolated from Helicobacter pylori but claims polypeptides that are cross reactive with other polypeptides and shares from 60 % sequence identity with SEQ ID NO 764 and claims polypeptides with, from 10 amino acids of SEQ ID No 764. No single functional characteristic of SEQ ID NO 764 is ascribed to the claimed polypeptide other than antigenicity. Note that while the specification produces the full-length polypeptide recombinantly, no biological activity is established for the full-length polypeptide or any of the claimed fragments thereof 10 amino acids or more. Circular reasoning to define a utility does not define a substantive utility. For example, when a polypeptide or antigen fragment is used to stimulate the production of antibodies so the antibodies can be used to identify the polypeptide, the use of the polypeptide is not specific or substantial to anything other than a polypeptide that does not correlate with anything other than itself. If no information is provided describing where or how the polypeptide is presented or functions, the use of the polypeptide as a specific marker for diagnostic purposes could not be carried out. As polypeptides are known to be antigenic, the

characteristic of being a diagnostic marker for a bacterial infection or disease in not readily apparent merely by a composition being a polypeptide because all polypeptides are not diagnostic markers for infection and could be a polypeptide which shares cross reactivity with other bacteria. Therefore the polypeptide would not be specific for identifying the bacteria. If the assertion of a characteristic is credible, the claimed invention would also need to evidence specific utility for claimed subject matter. A person would not readily use a polynucleotide to produce a polypeptide that does not correlate with anything associated with a bacteria because the polypeptide has not been shown to be specific to that bacteria, nor has the polypeptide been shown to have any credible use that is substantially applicable for testing, discovering or associated with conditions that effect the context of its use. The instant specification does not disclose that the polynucleotide or polypeptide that it encodes correlates or has a well established utility known in the art as being specific, substantial and credible and would be readily apparent or implied by the properties of the material, alone or taken with the knowledge of one skilled in the art. As such, further research would be required to identify or reasonably confirm a "real world" context of use. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved would be required. It is noted that the specification provides no exemplification of any biological activity for the polypeptide of SEQ ID NO: 764. The specification provides no specific assays for any biological activity. Therefore, the specification does not fairly disclose a substantial utility for the claimed embodiments.

9. Claims 113-120, 123-125,127-135,149-150,196-213 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial, a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

10. Asserted utilities such as for cross reactive epitopes as well as gene probes and chromosomal markers are not specific as set forth in the guidelines.

11. Claims 113-120, 123,125,127-135,149-150,196-213 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a written description rejection.**

12. Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

The specification broadly describes as part of the invention isolated polypeptides encoded by polynucleotides for the claimed SEQ ID NO 764. The specification also broadly describes their novel polypeptide sequence encoded by a polynucleotide sequences (SEQ ID NO 764) The specification broadly describes polynucleotides encoding the polypeptides specifically include continuous or discontinuous regions encoding the polypeptide and may also contain additional

coding and non-coding regions. First, it is evident from the instant that applicant is describing their novel sequence (SEQ ID NO:764) and generically by reference to a polynucleotide sequence encoding the novel polypeptide sequence and that such language is intended to encompass the "gene" including coding or non-coding sequences. Applicant also broadly describe the invention as embracing any substitution, insertion or deletion change of nucleotides throughout the entire stretch of nucleotides found in the reference sequence by use of language in which a specified number of nucleotides can be changed and the use of vectors, host cells in methods of producing the polypeptide. The claims encompass polypeptides obtained from polynucleotide sequences *comprising* which hybridize under stringent conditions with SEQ ID NO:764, sequences that have a recited degree of change as compared to a reference nucleic acid sequence that encodes the polypeptide of SEQ ID NO:764, sequences that hybridize to the full complement of SEQ ID NO: 764 and may or may not have the same biological function and *would be encoded by* nucleic acids . None of these sequences meets the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

The specification only discloses a polypeptide sequence encoded by a polynucleotide sequence consisting of SEQ ID NO: 764 which corresponds to the polynucleic acid sequence encoding the Helicobacter pylori polypeptide. An isolated polynucleotide consisting of a nucleotide sequence encoding SEQ ID NO:764, is also described by way of the written description in view of the art established principle of wobble variants of triplet codons for particular human amino acids as described in basic textbooks. Thus, an isolated polynucleotide sequence consisting of SEQ ID NO: 764 and an isolated polynucleotide consisting of a nucleotide sequence encoding SEQ ID NO:764 meets the written description provision of 35 U.S.C. 112, first paragraph.

The specification does not provide written description support for any flanking nucleic acid sequences which are 5' or 3' of the polynucleotide that encodes a polypeptide of SEQ ID NO:764. With the exception of an isolated polypetide that is encoded by a polynucleotide consisting of SEQ ID NO:764. The skilled artisan cannot envision all the contemplated nucleotide sequences by the detailed chemical structure of the claimed polynucleotides and therefore conception cannot be not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In

Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. Similarly, applicants have not disclosed any information which is 3' and 5' to the polynucleotide sequence of SEQ ID NO:764 and therefore clearly lacks written description for the broad class of polynucleotides comprising SEQ ID NO:764. Thus, the written description of the instant specification does not provide for "comprising" language. In the instant case the specification provides only written description for a polypeptide that is encoded by a polynucleotide consisting of SEQ ID NO:764.

Therefore, only an isolated polypeptide encoded by a polynucleotide consisting of SEQ ID NO: 764 and an isolated polynucleotide consisting of a nucleotide sequence encoding SEQ ID NO:764, but not the full breadth of the claim meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision.

Conclusion

This a non-final rejection. No claims are allowed.

13.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner

can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be changing February 7, 1998. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1641.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

~~June 28, 1999~~

James C. Housel 4/24/00

JAMES C. HOUSEL
SUPERVISORY PATENT EXAMINER